

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

**WARNER CHILCOTT LABS. IRELAND,  
*et al.*,**

**Plaintiffs,**

**v.**

**IMPAX LABORATORIES, INC., *et al.*,**

**Defendants.**

**Civil Action Number:  
(CONSOL.)**

**2:08-cv-06304-WJM-MF**

**2:09-cv-00228-WJM-MF**

**2:09-cv-00469-WJM-MF**

**2:09-cv-01233-WJM-MF**

**2:09-cv-02073-WJM-MF**

**OPINION**

**HON. WILLIAM J. MARTINI**

**OPINION**

This matter comes before the Court on the parties' submissions seeking construction of five disputed claim terms found in the patent-in-suit. Having taken into consideration the parties' submissions and their arguments made during the *Markman*<sup>1</sup> hearing held on July 11, 2011, the Court construes the disputed claim terms as set out below.

**I. BACKGROUND**

Five Hatch-Waxman Act patent suits were consolidated for discovery purposes. These include: *Warner Chilcott Labs. Ireland, et al. v. Impax Labs., Inc., et al.*, Civil Action No. 2:08-cv-06304-WJM-MF (consol.); *Warner Chilcott Labs. Ireland, et al. v. Sandoz Inc.*, Civil Action No. 2:09-cv-00228-WJM-MF; *Warner Chilcott Labs. Ireland, et al. v. Actavis Elizabeth LLC, et al.*, Civil Action No. 2:09-cv-00469-WJM-MF;<sup>2</sup> *Warner Chilcott Labs. Ireland, et al. v. Impax Labs., Inc.*, Civil Action No. 2:09-cv-01233-WJM-MF; and *Warner Chilcott Labs. Ireland, et al. v. Mylan Pharms., Inc., et al.*, Civil Action No. 2:09-cv-02073-WJM-MF. The patent at issue in each case is: United States Patent No. 6,958,161 (October 25, 2005).

*Patent No. 6,958,161 ('161 Patent)*. Plaintiffs' '161 Patent is titled "Modified Release Coated Drug Preparation." The drug product provides a "modified" or "delayed release" of an active ingredient, i.e., an antibiotic tetracycline. The drug product makes use of a "stabilizing coat" between the core element containing the active ingredient and the

<sup>1</sup> *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (en banc).

<sup>2</sup> This case has already been dismissed.

modified release coating. “As with all pharmaceutical preparations, an important aspect . . . is the stability over extended periods of time, which is often called ‘shelf life’. Typically, a [pharmaceutical] preparation’s shelf life is linked to two aspects; firstly, the stability of the ingredients themselves, namely the maintenance of their . . . properties over time; and secondly, the maintenance over time of the originally intended rate of drug release from the dosage form. This present invention is directed towards this second aspect of stability.” Patent, col. 1, ll. 22-32. The claimed invention creates a preparation that is stable, i.e., the active ingredient’s release profile is substantially the same even after the drug product has been stored for an extended period of time.

Defendants filed Abbreviated New Drug Applications with the U.S. Food and Drug Administration seeking approval to market generic versions of Plaintiffs’ patented Doryx products. Plaintiffs assert infringement of the ‘161 Patent; Defendants assert the Patent is invalid, unenforceable, and/or not infringed.

Disputed terms include: (i) “a modified release preparation;” (ii) “modified release coating;” (iii) “delayed release coating;” (iv) “core element;” and (v) “stabilizing coat is provided between each core element and its modified release coating so that.”

## **II. STANDARD OF REVIEW FOR DISPUTED CLAIM TERMS**

The objective of claim construction is to determine how a person of ordinary skill in the art would understand the claim terms. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313, 1324 (Fed. Cir. 2005) (en banc). Generally, claim terms are given their ordinary and customary meaning. *Id.* at 1312-13 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). That meaning “is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips*, 415 F.3d at 1313. In determining the ordinary meaning of a disputed claim term, the person of ordinary skill in the art is deemed to read the disputed claim terms in the context of the entire patent, including the particular claims in which the claim terms appear, the remaining claims, and the specification. *Id.* at 1313.

The claims “provide substantial guidance as to the meaning of particular claim terms.” *Id.* at 1314. Oftentimes, the context in which a term is used in asserted and unasserted claims “can be highly instructive.” *Id.* Further, differences among claims can provide useful insight into a term’s meaning. *Id.*

But the claims cannot be looked at in isolation; rather, the claims must be considered in view of the specification. *Id.* at 1315. The specification is considered to be the “single best guide” for construing the claims. *Id.* The specification may reveal whether the patentee acted as his own lexicographer by giving a claim term a special definition. *Id.* Or, it may show that the patentee intentionally disclaimed claim scope. *Id.* In either case, the patentee’s intent is dispositive. *Id.*

A court should also consider the prosecution history, if it is in evidence. *Id.* at 1317. The prosecution history “consists of the complete record of the proceedings before the [Patent

and Trademark Office (PTO)] and includes the prior art cited during the examination of the patent.” *Id.* (citing *Autogiro Co. of Am. v. United States*, 384 F.2d 391, 399 (Ct. Cl. 1967)). Although it “often lacks the clarity of the specification and thus is less useful for claim construction purposes,” the prosecution history sheds light on the PTO and inventor’s understanding of the patent. *Phillips*, 415 F.3d at 1317.

A court may, in its discretion, consult extrinsic evidence, i.e., dictionaries, treatises, and expert and inventor testimony, when construing claim terms. *Id.* “The purpose of expert testimony is to provide assistance to the court in understanding, when the claims are technologically complex or linguistically obscure, how a technician in the field, reading the patent, would understand the claims.” *Advanced Cardiovascular Sys., Inc. v. Scimed Life Sys., Inc.*, 887 F.2d 1070, 1076 (Fed. Cir. 1989) (Newman, J., dissenting). Although extrinsic evidence may be used in claim construction, it may not be used to vary or contradict the intrinsic evidence. *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1308 (Fed. Cir. 1999); *Phillips*, 415 F.3d at 1324. A court may consult extrinsic evidence to educate itself about the field of the invention and to aid its understanding of what one of ordinary skill in the art would understand a claim term to mean. *Id.* at 1319. But extrinsic evidence is “less significant” and “less reliable” than intrinsic evidence because it gives meaning to a claim term in the abstract, rather than in the particular context of the patent. *Id.* at 1317-18. Thus, extrinsic evidence may play only a supporting role in claim construction. *See id.* at 1324. The Federal Circuit reestablished the primacy of the intrinsic evidence – the claims, specification and prosecution history – and, as explained, classified dictionaries as part of the less significant extrinsic evidence. *Id.* at 1312.

### III. DISCUSSION AND RESOLUTION OF THE DISPUTED CLAIM TERMS

#### A. A Modified Release Preparation<sup>3</sup>

Contentions of the Parties. Plaintiffs’ proposed construction of “a modified release preparation” is *a preparation that provides a release profile for an active ingredient that is different from that of an immediate release preparation*. Defendants argue that this preamble term is not limiting, and therefore, it should not be construed. However, Defendants do not otherwise dispute Plaintiffs’ construction, and, for example, do not propose an alternative construction in the event that the Court should decide that this

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<sup>3</sup> See, e.g., Patent, claim 1, col. 12, ll. 36-45:

A modified release preparation having one or more core elements, each core element comprising an active ingredient selected from the group containing of the acid salts of doxycycline . . . and having a modified release coating, wherein a stabilizing coat is provided between each core element and its modified release coating so that, upon in vitro dissolution testing, the amount of active ingredient released at any time on post-storage dissolution profile is within 40 percentage points of the amount of active ingredient released at any time on a pre-storage dissolution profile.

preamble phrase is limiting.

Claim Construction Analysis for *Modified Release Preparation*. “Generally speaking, there are three parts to every claim: the preamble, the transitional phrase, and the body. The transitional phrase, e.g., ‘comprising’ or ‘consisting of,’ connects the preamble to the body of the claim. The preamble is the portion of the claim that includes everything before the transitional phrase. The body is everything after the transitional phrase.” *Intell-A-Check Corp. v. Autoscribe Corp.*, 346 F. Supp. 2d 698, 704 (D.N.J. 2004). If the preamble does not give “life, meaning and vitality to the claim,” the preamble is considered to be “of no significance to claim construction because it cannot be said to constitute or explain a claim limitation.” *Altiris, Inc. v. Symantec Corp.*, 318 F.3d 1363, 1371 (Fed. Cir. 2003). In order to determine whether the preamble should constitute a limitation, and therefore requires construction, the Court must look to the “overall form of the claim, and the invention as described in the specification and illuminated in the prosecution history.” *Id.* When the preamble merely states a “purpose or intended use for the invention,” it is not limiting. If it recites an essential structure or step, it is limiting. *Catalina Mktg. Int’l v. Coolsavings*, 289 F.3d 801, 808 (Fed. Cir. 2002). “Likewise, when the preamble is essential to understand limitations or terms in the claim body, the preamble limits claim scope.” *Id.*

First, Defendants use the disputed phrase – *modified release preparation* – in their proposed construction for “core element,” another disputed claim term. That would seem to imply that *modified release preparation* requires construction.<sup>4</sup> *Cf. id.* at 810 (holding that a preamble term was not limiting because the patent applicant “did not rely on this phrase to define its invention”). Second, certain dependent claims (implicitly) refer back to *modified release preparation*. For example, claim 6 states: “6. The preparation according to claim 1,” Patent, claim 6, col. 12, l. 65, and claim 1 makes use of the disputed term: “modified release preparation,” Patent, claim 1, l. 1. *See, e.g., Sunbeam Prods., Inc. v. Delonghi Am., Inc.*, 2007 U.S. Dist. LEXIS 123, at \*14 (D.N.J. Jan. 3, 2007) (NOT PUBLISHED). This too would seem to indicate that *modified release preparation* requires construction. Finally, Defendants’ responsive brief does not appear to contest Plaintiffs’ position on this issue.

For these reasons, the Court will construe this term and will adopt Plaintiffs’ proposed construction.

#### B. *Modified Release Coating*<sup>5</sup>

<sup>4</sup> This reason would be highly significant, if not dispositive, if the Court relied on Defendants’ construction for “core element.” As explained below, the Court will reject Defendants’ proposed construction of that disputed claim term.

<sup>5</sup> *See, e.g.,* Patent, Detailed Description of the Invention, col. 7, ll. 19-27:

The modified release coating may also be any suitable coating material, or combination of coating materials, that will provide the desired modified release profile. For example, coatings such as enteric coatings, semi-enteric

Contentions of the Parties. Plaintiffs' proposed construction of a "modified release coating" is *material(s) that provide(s) a desired modified release profile for an active ingredient*.

Defendants' proposed construction is *any layer disposed on a substrate that affects the release of the active ingredient from the core element*.

The Court construes a "modified release coating" to mean *a layer of material(s) that provide(s) a desired modified release profile for an active ingredient*.

Claim Construction Analysis for a *Modified Release Coating*. Plaintiffs' proposed construction drops the use of "coating," and the term coating (and, layer,<sup>6</sup> its synonym<sup>7</sup>) appears throughout the claims and specification. The Court's use of "layer" in place of "coating" is supported both by general dictionaries<sup>8</sup> and scientific dictionaries.<sup>9</sup> Plaintiffs' use of "material," by contrast, lacks support in the patent's language and in the extrinsic evidence. Indeed, Plaintiffs' brief identifies "coating" with "layer."<sup>10</sup>

Defendants' *disposed on a substrate*-language departs very far from the language

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coatings, delayed release coatings or pulse release coatings may be desired. In particular, a coating will be suitable if it provides an appropriate lag in active release prior to the rapid release at a rate essentially equivalent to immediate release of the active ingredient.

<sup>6</sup> THE AMERICAN HERITAGE DICTIONARY 719 (2d college ed. 1985) (defining "layer" as "1. A single thickness, coating, or stratum spread out or covering a surface"); THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 994 (4th ed. 2009) (defining "layer" as "2a. A single thickness of a material covering a surface or forming an overlying part or segment"); 1 THE COMPACT EDITION OF THE OXFORD ENGLISH DICTIONARY 133 (1971) (defining "layer" as "II[2] A thickness of matter spread over a surface; *esp.* one of a series of such thicknesses; a stratum"); THE RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE 1091 (unabridged 2d ed. 1987) (defining "layer" as "1. a thickness of some material laid on or spread over a surface . . . . 2. bed; stratum . . . . 8. to make a layer of").

<sup>7</sup> See, e.g., Pls.' Opening Br. 16 (referring to the *modified release coating* as a *modified release layer*).

<sup>8</sup> See, e.g., THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE, *supra* note 6, at 354 (defining "coating" as "a layer of a substance spread over a surface for protection or decoration; a covering layer"); 1 THE COMPACT EDITION OF THE OXFORD ENGLISH DICTIONARY, *supra* note 6, at 558 (defining "coating" as "1. A layer of any substance spread over or covering a surface"); THE RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE, *supra* note 6, at 394 (defining "coating" as "1. a layer of any substance spread over a surface").

<sup>9</sup> See, e.g., RICHARD J. LEWIS, SR., HAWLEY'S CONDENSED CHEMICAL DICTIONARY 279 (13th ed. 1997) (defining "coating" as "[a] film or thin layer applied to a base material").

<sup>10</sup> See *supra* note 7.



appearing in the Patent. Defendants also argue that the examples in the Preferred Embodiment section state, in each case, that the *modified release coat* is applied to the core element after the stabilizing coat is applied. Patent, col. 9, ll. 13-14 (“The modified release coat is applied to the stabilizing coated core elements using a fluidized bed coating process . . . .”); col. 10, ll. 54-55 (“Once the stabilizing coat is dry, the coated core element . . . is then coated with the modified release coat . . . .”). Defendants’ reliance on the description in the Preferred Embodiment section appears to be misplaced. The fact that the examples in the Preferred Embodiment reflect the deliberate, intentional application of the *modified release coating* onto an already coated core element does not expressly disclaim wider scope in the claims. *Electro Med. Sys., S.A. v. Cooper Life Sciences, Inc.*, 34 F.3d 1048, 1054 (Fed. Cir. 1994) (noting that “particular embodiments appearing in a specification will not be read into the claims when the claim language is broader than such embodiments”). The preferred embodiments language referenced by Defendants do not expressly disclaim wider scope, i.e., where the intermediate stabilizing coat forms *in situ* between an outer modified release coating and an inner core element.

Similarly, Defendants argue that the Patentee acted as his own lexicographer and described the *modified release coating* as a “coating layer.” Patent, col. 7, l. 52. In other words, Defendants are arguing that the “coating layer” language implies that a distinct process is used to apply this layer onto the core element (ostensibly, after the stabilizing coat is applied). Defendants’ construction appears to add an impermissible process limitation into the claim. *Sanofi-Aventis U.S. LLC v. Sandoz, Inc.*, 345 Fed. Appx. 594, 597-98 (Fed. Cir. Sept. 10, 2009) (injecting a process limitation is error where “the patent specification and prosecution history focus on the property of the composition . . . and not the process used to obtain that property.”). The fact that a *modified release coating* is described as a “coating layer” does not, without more, establish that it is physically applied as a distinct layer or at a distinct stage.

Defendants object to Plaintiffs’ using *desired*, and instead suggest using *affect*. Plaintiffs’ position is supported by the intrinsic evidence, *see, e.g.*, Patent Specification, col. 7, ll. 19-27, and by one of Defendants’ exhibits, *see, e.g.*, Defs.’ Opening Br., Ex. C at 411.

Finally, the remainder of the language in the Court’s proposed construction – *desired modified release profile* – is supported by the specification. *See supra* note 5 (quoting Patent Specification, col. 7, ll. 19-27).

### C. Delayed Release Coating

Contentions of the Parties. Defendants’ proposed construction of a “delayed release coating” is *any layer disposed on a substrate that slows the release of the active ingredient from the core element*.

Plaintiffs’ proposed construction is *a modified release coating that slows the release of active ingredient in the stomach or other acidic media compared to an immediate release preparation*.

The Court construes “delayed release coating” to mean *a layer of material(s) that slows*

*the release of active ingredient in the stomach*<sup>11</sup> *or other acidic media as compared to an immediate release preparation.*

Claim Construction Analysis for *Delayed Release Coating*. The issues here are largely duplicative with the issues discussed in Section III[B] – *Modified Release Coating*. Plaintiffs’ definition makes use of language in the specification. Patent, col. 2, ll. 55 – col. 3, l. 6. Plaintiffs’ use of *or other acidic media* is supported by expert testimony. See McGinity Decl. ¶ 45, Jan. 18, 2010. Defendants do not expressly contest this point, i.e., relating to *other acidic media*.

Likewise, Defendants’ *disposed on a substrate*-language incorporates process limitations and departs from the language in the specification. Finally, for the reasons already explained, the Court defines “coating” in terms of “layer.”<sup>12</sup>

#### *D. Core Element*<sup>13</sup>

Contentions of the Parties. Defendants’ proposed construction of “core element” is *the component of a modified release preparation that provides the active ingredient, that may contain other ingredients, and that forms the substrate of a coating layer.*

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<sup>11</sup> See, e.g., Patent, Summary of the Invention, col. 2, ll. 55 – col. 3, l. 6:

Modified release preparation in accordance with the present invention will typically be such as to provide a delayed release of the active ingredient, with reference to the active ingredient’s dissolution profile. In this respect, where the modified release is such as to provide a delayed release (generally referred to as a ‘delayed release preparation’) the preparation aims to slow the release of the active [ingredient] in the stomach to minimize the side effects of the active [ingredient] that may be caused by release of the active [ingredient] in the stomach. Such side effects include nausea and gastrointestinal irritation.

Most delayed release preparations aim for the drug to be released in the upper regions of the small intestines, for a number of reasons, as follows: the drug is able to start working as soon as possible after ingestion without side effects caused by drug being released in the stomach; the conditions in the upper small intestine are usually optimum for drug absorption; and to avoid acid degradation of the drug in the stomach.

<sup>12</sup> See *supra* notes 6-10, and accompanying text.

<sup>13</sup> See, e.g., Patent, Summary of the Invention, col. 1, ll. 56-60:

The present invention provides a modified release preparation having one or more coated core elements, each core element including an active ingredient and having a modified release coating, wherein a stabilizing coat is provided between each core element and its modified release coating . . . .

See also, e.g., Patent, claim 1, col. 12, ll. 36-43 (same).

Plaintiffs' proposed construction is *an element comprising an active ingredient*.

The Court construes "core element" to mean *a component comprising an active ingredient*.

Claim Construction Analysis for *Core Element*. Defendants' construction appears overly narrow. First, the *provides the active ingredient* language seems to imply that when released the active ingredient is only in the core. There is some language that supports such a construction. *See* Patent, col. 5, l. 54 ("The core elements provide the active ingredient."). *But see* Patent, col. 6, l. 57-59 ("The purpose of the stabilizing coat is to keep the active ingredient and the modified release coating separated. . . . The stabilizing coat is intended to keep the migration of the core materials to a minimum such that interaction with coating materials [including, apparently, the stabilizing coat and the modified release coating] is reduced or prevented . . ."). In context, it would seem that although the active ingredient initially is associated with the core, over time it may migrate to the coating materials, i.e., the stabilizing coat, and the modified or delayed release coating. For that reason Defendants' use of *provides* does not appear to be correct. Likewise, describing the *core element* as a substrate of a coating layer is well beyond the language of the Patent. Plaintiffs dispute this "substrate" language in large part because Defendants' language might appear to import a process limitation into claim construction language – i.e., the core is made first, the stabilizing coat is applied afterwards, and finally the modified release coating is applied. This Patent is for a composition, not a process. Such limitations do not appear to be proper.

Finally, in defining "element," the Court uses the term "component." This is supported by popular usage and dictionaries.<sup>14</sup>

*E. Stabilizing Coat Is Provided Between Each Core Element And Its Modified Release Coating So That*<sup>15</sup>

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<sup>14</sup> *See, e.g.*, THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE, *supra* note 6, at 577 (defining "element" as "[a] fundamental, essential, irreducible constituent of a composite entity"); THE RANDOM HOUSE DICTIONARY OF THE ENGLISH LANGUAGE, *supra* note 6, at 630 (defining "element" as "a component or constituent of a whole or one of the parts into which a whole may be resolved by analysis").

<sup>15</sup> *See, e.g.*, Patent, claim 1, col. 12, ll. 36-45:

A modified release preparation having one or more core elements, each core element comprising an active ingredient selected from the group containing of the acid salts of doxycycline . . . and having a modified release coating, wherein a stabilizing coat is provided between each core element and its modified release coating so that, upon in vitro dissolution testing, the amount of active ingredient released at any time on post-storage dissolution profile is within 40 percentage points of the amount of active ingredient released at any time on a pre-storage dissolution profile.



Contentions of the Parties. Defendants' proposed construction of a "stabilizing coat is provided between each core element and its modified release coating so that" is *an inert barrier layer, disposed on and distinct from the core element, that separates and seals the core element from the modified release layer to provide the claimed post-storage dissolution stability.*

Plaintiffs' proposed construction is *material(s), in contact with an element comprising an active ingredient, reduce(s) or prevent(s) undesired interactions, including the migration of moisture or solvent, between that element and the modified release coating so that.*

The Court construes the disputed claim term to mean *a layer of material(s) between each core element and its modified release coating, which keeps the migration of core materials to a minimum such that the interaction of core materials with coating materials is reduced or prevented so that.*

Claim Construction Analysis for *Stabilizing Coat Is Provided Between Each Core Element And Its Modified Release Coating So That*. Defendants' proposed construction makes use of "inert barrier" to construe the disputed claim term. This is overly restrictive. It is true that the "inert barrier" language is used in the specification, but it appears in a sentence using the permissive "may," not the mandatory "shall." Also, the inert "barrier language" is contradicted (to the extent that "inert" means wholly inert) by much other language in the specification indicating that the stabilizing coat is intended to "reduce or prevent" the "interaction" of core materials with coating materials. This would seem to

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*See also, e.g., Patent, Detailed Description of the Invention, col. 6, l. 53 – col. 7, l. 7:*

The stabilizing coat is a physical barrier between the active ingredient and the modified release coating. The stabilizing coat may also be referred to as a seal coat or any intermediary layer.

The purpose of the stabilizing coat is to keep the active ingredient and the modified release coating separated. In this respect, it is believed that the stabilizing coat slows migration of moisture or solvent between the modified release coating and the active ingredient. Whilst the stabilizing coat will preferably keep the active ingredient separated from the modified release coating during storage, the stabilizing coat will ideally not interfere significantly with the rate of release of the active ingredient, and therefore should be at least semi-permeable in aqueous media and may even be soluble. Indeed, the stabilizing coat is intended to keep migration of core materials to a minimum such that their interaction with coating materials is reduced or prevented, whilst still allowing for release of core materials into an aqueous environment.

The stabilizing coat may thus be any suitable material which makes an inert barrier between the core element, or the active ingredient containing layer, and the modified release coating . . . .

indicate that the barrier is not wholly inert. Defendants' use of "separates" and "seals" is also too restrictive for the same reasons, notwithstanding that there is some language using such terms in the specification. *See* Patent, col. 6, ll. 54-56 ("The stabilizing coat may also be referred to as a seal coat or any intermediary layer."). Defendants' use of "disposed on and distinct from" should also be rejected. It strongly departs from the Patent's language and seems to introduce a process limitation, where the Patent is for a composition. Finally, Defendants' proposed construction states that the purpose of the stabilizing coat is "to provide the claimed post-storage dissolution stability." This seems incorrect. It appears that the better reading of the Patent's language is that the *modified release preparation* as a whole *provide[s] the claimed post-storage dissolution stability*, not the stabilizing coat standing alone. This view appears to be supported even by Defendants' expert, Dr. Kibbe. *See* Kibbe Tr. 182:14-15. However, Defendants' proposed language describes the "stabilizing coat" as a "layer." This seems correct and is supported by much language in the Patent. *See* Patent, col. 6, ll. 54-56 ("The stabilizing coat may also be referred to as a seal coat or any intermediary *layer*." (emphasis added)).

Plaintiffs' construction refers to the stabilizing coat as "material(s), in contact with an element comprising an active ingredient." Plaintiffs' "in contact" language is overbroad in the extreme. The Patent describes the "stabilizing coat" as a "coat." Frequently the Patent uses language referring to the coats in terms of "layers." *E.g. id.*<sup>16</sup> Plaintiffs' proposed language fails to refer to this coat in terms of layers. More importantly, Plaintiffs' proposed construction does not indicate the location of the stabilizing coat: which is, according to the Patent, "between" the core and its modified release coating.

Plaintiffs' construction also states that the stabilizing coat "reduce(s) or prevent(s) undesired interactions, including the migration of moisture or solvent." But the Patent does not state that the stabilizing coat achieves those goals, it only states that "it is *believed* that the stabilizing coat slows migration of moisture or solvent." Instead, the Court relies on language in the specification which describes the stabilizing coat's intended function: "Indeed, the stabilizing coat is intended to keep migration of core materials to a minimum such that their interaction with coating materials is reduced or prevented . . . ." Patent, Detailed Description of the Invention, col. 6, l. 67 – col. 7, l. 3.

#### IV. CONCLUSIONS

For the reasons elaborated above, the Court construes the disputed claim terms as follows:

- (1) "a modified release preparation" means *a preparation that provides a release profile for an active ingredient that is different from that of an immediate release preparation*;
- (2) "modified release coating" means *a layer of material(s) that provide(s) a desired modified release profile for an active ingredient*;

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<sup>16</sup> *See also supra* note 6 (illustrating dictionary definitions of "layer"); *see also supra* notes 8-9 (reproducing scientific and general dictionary definitions of "coating").

(3) “delayed release coating” means *a layer of material(s) that slows the release of active ingredient in the stomach or other acidic media as compared to an immediate release preparation;*

(4) “core element” means *a component comprising an active ingredient;*

and,

(5) “stabilizing coat is provided between each core element and its modified release coating so that” means *a layer of material(s) between each core element and its modified release coating, which keeps the migration of core materials to a minimum such that the interaction of core materials with coating materials is reduced or prevented so that.*

An appropriate order follows.

**DATE: July 20, 2011**

s/ William J. Martini  
**William J. Martini, U.S.D.J.**